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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,874	10/11/2001	Kaori Ishimaru	10873.796USWO	5628

7590 12/09/2003  
Merchant & Gould  
PO Box 2903  
Minneapolis, MN 55402-0903

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

9.14.

**Office Action Summary**

Application No.

09/913,874

Applicant(s)

ISHIMARU ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

Claims 1-15 are pending. Claims 1-8 are considered on the merits. Claims 9-15 are withdrawn from consideration as being drawn to a non-elected invention.

#### ***Election/Restriction***

Claims 9-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group, the requirement having been traversed in Paper No. 9.

Claim 9 may be rejoined upon the finding of an allowable enzyme, if it is limited to a composition comprising the allowable enzyme.

#### ***Claim Rejections – 35 USC § 102***

Claims 1 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/48043 [N].

The claims are directed to a protease which releases an amino acid having a glydated  $\alpha$ -amino group fro a glydated protein or peptide and a method for quantitating a glydated protein comprising treating the sample with a protease that hydrolyzes the amino acid having a glydated  $\alpha$ -amino group and treating the hydrolyzed sample with fructosyl amino acid oxidase to catalyze a redox reaction and quantitating the reaction.

The references are relied upon as explained below.

WO 98/48043 in Table 1 and Table 2 discloses various proteases which have been used to hydrolyze glydated proteins. While the reference does not reveal whether or not the proteases are capable of releasing a single glydated amino acid, the proteases listed (1) have been used to determine the amount of glydated protein in the same test method as the instant one; and (2) the proteases listed are fairly non-specific, so that given enough time, a single glydated amino acid, such as a glydated valine if present, could reasonably be expected to be released from a glydated protein.

Insofar as these processes rely on the use of an enzyme which instead of being characterized by technical features suitable for the identification of an enzyme, is imprecisely defined by means of functional features which merely recite the desired result to be achieved, the subject matter is considered to be anticipated by the disclosures of the prior art until objective evidence is presented to disprove this reasonable assumption. Further, as the trade names for the enzymes are used, it is unclear if any of these are derived from the genus *Pseudomonas* or *Corynebacterium*. It is assumed that at least some of them are until a clear statement to the contrary is provided.

### ***Response to Arguments***

Applicants argue that WO 98/48043 does not disclose *P. alcaligenes* KDK1001 (FERM-P-17133). While the strain of bacteria from which the enzyme is obtained may not be the same in the cited art, it is unclear if any of the enzymes cited in WO 98/48043 are obtained from *P. alcaligenes*. If none of the enzymes are obtained from the same genus and species, namely *P. alcaligenes*, a clear statement of the genus/species from which each of the FAOD enzymes in the references is obtained would remove this reference. Applicants also argue that the reference does not teach removal of an amino acid from an alpha amino acid glycosylated protein. Accordingly, the examiner, unable to read Japanese, accepts this statement and the rejection over the method claims is withdrawn.

Claims 1, 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shin *et al.* [IDS].

The claims are directed to a protease obtained from a strain of *Pseudomonas alcaligenes* having the ability to release an amino acid having a glycosylated  $\alpha$ -amino group from a glycosylated protein.

Shin *et al.* disclose a protease derived from a strain of *P. alcaligenes* which has the ability to hydrolyze various proteins.

### ***Response to Arguments***

Applicants have not demonstrated that their protease is distinct from the protease of the reference and therefore, have not met their burden of establishment of novelty by objective evidence.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' enzyme differs and, if so, to what extent from the enzymes discussed in the references. Accordingly, it has been established that the prior art enzymes, which are obtained from the same genus and species and share the property of being able to hydrolyze proteins demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known enzyme is not disclosed in a reference does not make the known enzyme patentable. The known enzyme possesses inherent characteristics which might not be displayed in the tests used the reference. However, the enzyme disclosed may be the same enzyme as claimed. Clear evidence that the enzymes of the cited prior art do not possess a critical characteristic that is possessed by the claimed enzyme, would advance prosecution and might permit allowance of some of the claims.

#### ***Allowable Subject Matter***

Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the

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advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, flowing script.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
December 4, 2003